Catalyzing Translational Innovation

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NATIONAL CENTER FOR ADVANCING TRANSLATIONAL SCIENCES
NATIONAL INSTITUTES OF HEALTH

HEALTH RESEARCH ALLIANCE MEMBERS’ MEETING
SEPTEMBER 28, 2016
The Best of Times, the Worst of Times

Fundamental science unprecedentedly advanced, but:

- Poor transition of basic or clinical observations into interventions that tangibly improve human health
- Drug/device/diagnostic development expensive and failure-prone
- Clinical trials system inefficient
- Poor adoption of demonstrably useful interventions

People unhealthier and funders of biomedical research enterprise (public and private) impatient
Human Conditions with Known Molecular Basis

Source: Online *Mendelian Inheritance in Man*, Morbid Anatomy of the Human Genome
Moore's Law

The diagram illustrates the trend of transistor count doubling every two years from 1971 to 2011. The curve shows the exponential growth in transistor count over time, highlighting the advancements in technology as represented by various processor models.

Eroom’s Law

The number of new drugs approved by the FDA per billion US dollars (inflation-adjusted) spent on research and development (R&D) has halved roughly every 9 years since 1950.

NCATS Mission

To catalyze the generation of innovative methods and technologies that will enhance the development, testing and implementation of diagnostics and therapeutics across a wide range of human diseases and conditions.
What is Translation?

Translation is the process of turning observations in the laboratory, clinic, and community into interventions that improve the health of individuals and the public - from diagnostics and therapeutics to medical procedures and behavioral changes.
What is Translational Science?

*Translational Science* is the field of investigation focused on understanding the scientific and operational principles underlying each step of the translational process.

NCATS studies translation as a scientific and organizational problem.
Some of the **scientific** translational problems on NCATS’ to-do list

- Predictive toxicology
- Predictive efficacy
- Derisking undruggable targets/untreatable diseases
- Data interoperability
- Biomarker qualification process
- Clinical trial networks
- Patient recruitment
- Electronic Health Records for research
- Harmonized IRBs
- Clinical diagnostic criteria
- Clinical outcome criteria (e.g., PROs)
- Adaptive clinical trial designs
- Shortening time of intervention adoption
- Methods to better measure impact on health (or lack of)
Some of the organizational translational problems on NCATS’ to-do list...

- Data transparency/release
- IP management
- Integration of project management
- Incentives/credit for team science
- Incentives/credit for health improvements
- Education/Training (scientific and cultural)
- Collaborative structures
  - Public-private partnership models
NCATS “3D’s”

Develop
Demonstrate
Disseminate
NCATS Scientific Initiatives

• Clinical Translational Science
  » Clinical and Translational Science Awards
  » Rare Disease Clinical Research Network
  » New Therapeutic Uses program

• Preclinical Translational Science
  » NCATS Chemical Genomics Center
  » Therapeutics for Rare and Neglected Diseases program
  » Bridging Interventional Development Gaps program

• Re-engineering Translational Sciences
  » Toxicology in the 21st Century
  » Microphysiological Systems (Tissue Chip) program
  » Office of Rare Diseases Research
Division of Clinical Innovation

Clinical and Translational Science Awards (CTSA) Program

• A national consortium of medical research institutions
• Improves the way clinical and translational research is conducted nationwide
• Accelerates the research translation process
• Provides innovative training for clinical and translational researchers
Collaborative Consortium for Translational Research

Building on local and regional strength to bring more discoveries to health benefit:

- Form virtual teams
- Share information, practices, tools
- Connect data systems
- Implement efficient multisite studies
- Integrate care and research
- Have greater impact together
NCATS Trial Innovation Network

The Network will optimize clinical trials enterprise to accelerate translation

- Data-driven “learning clinical studies system” so trials can recruit more quickly, retain participants, finish on-time and on-budget, and produce impactful, high-quality data
- Leverage the talent, expertise & resources of the CTSA Program to transform clinical trials

Key components of the Network were awarded in July 2016

- **Recruitment Innovation Center (RIC):** develop and implement strategies to engage patients and communities in clinical trials
- **Trial Innovation Centers (TICs):** IRB, contracting, GCP training to improve efficiency and effectiveness of clinical studies
Some examples of CTSA Partnerships with Foundations

<table>
<thead>
<tr>
<th>CTSA</th>
<th>Engagement</th>
<th>Foundation Collaborator(s)</th>
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<tbody>
<tr>
<td>Rockefeller University</td>
<td>Pilot projects in digestive disease research, bio-medicine, and nutrition</td>
<td>Dracopolous Foundation; Helmsley Charitable Trust; Jumming Le Foundation; Niarchos Foundation; Robertson Foundation; Sackler Foundation; Vilcek Foundation</td>
</tr>
<tr>
<td>University of Washington</td>
<td>Program to organize and conduct free, monthly cardiovascular screenings at Seattle-area high schools</td>
<td>Nick of Time Foundation</td>
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<tr>
<td>University of Wisconsin–Madison</td>
<td>Pilot project to deliver family-centered diabetes self-management resources</td>
<td>Juvenile Diabetes Research Foundation</td>
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<td></td>
<td>Young investigator research training support</td>
<td>Cystic Fibrosis Foundation; Michael J. Fox Foundation</td>
</tr>
<tr>
<td>Washington University</td>
<td>Pilot projects, training awards</td>
<td>Barnes-Jewish Hospital Foundation</td>
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Office of Rare Diseases Research

- **Rare Diseases Clinical Research Network (RDCRN)**
  - 22 consortia at 250 institutions worldwide
  - Studying >200 diseases with 83 active protocols, and
  - More than 85 patient advocacy groups participating

- **Genetic and Rare Disease Information Center (GARD)**

- **Scientific Conferences Program**
  - Identify scientific opportunities and establish research agendas
  - Patients + NCATS + NIH ICs + FDA + Biopharma

- **Global Rare Disease Registry (GRDR)**
  - 15 GRDR patient registries + 19 existing registries
  - Ability to conduct cross-disease analysis and recruitment
<table>
<thead>
<tr>
<th>Consortium</th>
<th>Foundation Collaborator(s)</th>
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<tbody>
<tr>
<td>Advancing Research and Treatment for Frontotemporal Lobar Degeneration</td>
<td>Foundation for PSP CBD and Related Brain Disease</td>
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<tr>
<td>Autonomic Disorders</td>
<td>National Dysautonomia Research Foundation</td>
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<tr>
<td>Brain Vascular Malformation</td>
<td>Sturge-Weber Foundation</td>
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<tr>
<td>Brittle Bone Disorders</td>
<td>Osteogenesis Imperfecta Foundation</td>
</tr>
<tr>
<td>Clinical Research in Amyotrophic Lateral Sclerosis and Related Disorders</td>
<td>Spastic Paraplegia Foundation</td>
</tr>
<tr>
<td>Developmental Synaptopathies Consortium</td>
<td>PTEN Hamartoma Tumor Syndrome Foundation; Phelan-McDermid Syndrome Foundation</td>
</tr>
<tr>
<td>Dystonia Coalition</td>
<td>Dystonia Medical Research Foundation</td>
</tr>
<tr>
<td>Genetic Disorders of Mucociliary Clearance Consortium</td>
<td>Bronchiectasis Research Registry/COPD Foundation; Cystic Fibrosis Foundation; Heterotaxy Foundation; PCD Foundation</td>
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<tr>
<td>Inherited Neuropathies Consortium</td>
<td>Charcot Marie Tooth Association; Hereditary Neuropathy Foundation</td>
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<tr>
<td>Lysosomal Disease Network</td>
<td>Adrenoleukodystrophy Foundation; Ara Parseghian Medical Research Foundation; Ben’s Dream Sanfilippo Research Foundation; Cystinosis Foundation; Hide and Seek Foundation for Lysosomal Disease Research; Hunter’s Hope Foundation; Mucolipidosis IV Foundation; Nathan’s Battle Foundation; National Fabry Disease Foundation; National Gaucher Foundation; National Niemann-Pick Disease Foundation; Ryan Foundation; United Leukodystrophy Foundation</td>
</tr>
</tbody>
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## RDCRN Partnerships (cont’d)

<table>
<thead>
<tr>
<th>Consortium</th>
<th>Foundation Collaborator(s)</th>
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</thead>
<tbody>
<tr>
<td>Nephrotic Syndrome Study Network</td>
<td>Halpin Foundation</td>
</tr>
<tr>
<td>North American Mitochondrial Disease Consortium</td>
<td>United Mitochondrial Disease Foundation</td>
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<tr>
<td>Porphyrias Consortium</td>
<td>American Porphyria Foundation</td>
</tr>
<tr>
<td>Primary Immune Deficiency Treatment Consortium</td>
<td>Immune Deficiency Foundation; Jeffrey Modell Foundation; Wiscott-Aldrich Foundation</td>
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<tr>
<td>Rare Kidney Stone Consortium</td>
<td>International Cystinuria Foundation; Oxalosis and Hyperoxaluria Foundation</td>
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<tr>
<td>Rare Lung Diseases Consortium</td>
<td>Alpha-1 Foundation; Children’s Interstitial and Diffuse Lung Disease Foundation</td>
</tr>
<tr>
<td>Rett Syndrome, MECP2 Duplications, and Rett-related Disorders Consortium</td>
<td>International Foundation for CDKL5 Research; International FOXG1 Foundation</td>
</tr>
<tr>
<td>Sterol &amp; Isoprenoid Research Consortium</td>
<td>Ara Parseghian Medical Research Foundation; Foundation for Ichthyosis and Related Skin Types; Global Foundation for Peroxisomal Disorders; Sitosterolemia Foundation; Smith Lemli Opitz/RSH Foundation; United Leukodystrophy Foundation</td>
</tr>
<tr>
<td>Urea Cycle Disorders Consortium</td>
<td>National Urea Cycle Disorders Foundation</td>
</tr>
<tr>
<td>Vasculitis Clinical Research Consortium</td>
<td>Lauren Currie Twilight Foundation; Vasculitis Foundation</td>
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Rare Disease Patient Toolkit Project

- Provide centralized web portal to online tools and resources that patient groups can readily access to accelerate their work
- Focus on tools/resources across the drug development process
- “How-to” perspective, e.g. “How To Establish and Utilize a Patient Registry”
RD Patient Toolkit Being Developed through Community Engagement

- Working groups that represent diverse rare disease stakeholder community
- Conducting landscape analysis of current tools and resources for each phase of drug development process
- Gaps identified will be filled with new tool development
- Prototype demonstration/dissemination meeting Spring 2017

**Diagram:**

- Ascertain needs of patient groups
- Survey landscape of available tools
- Develop via calls & in-person meeting
- Disseminate and Demonstrate via larger meeting(s) & webinars
New Therapeutic Uses Program

80% of drugs that enter clinic are never approved

For every 1 drug approved, 4 late-stage investigational drugs available for new indication finding
New Therapeutic Uses Program

- 9 projects in 8 diseases funded in Round 1

<table>
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<tr>
<th>Disease</th>
<th>Academic Partner</th>
<th>Pharma Partner</th>
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<tbody>
<tr>
<td>Alzheimer’s Disease</td>
<td>Yale</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Alcoholism</td>
<td>U Rhode Island/NIAAA</td>
<td>Pfizer</td>
</tr>
<tr>
<td>Calcific Aortic Stenosis</td>
<td>Mayo Clinic</td>
<td>Sanofi</td>
</tr>
<tr>
<td>Duchenne Muscular Dystrophy</td>
<td>Kennedy Krieger/UWash</td>
<td>Sanofi</td>
</tr>
<tr>
<td>Lymphangioleiomyomatosis</td>
<td>Baylor</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Peripheral Artery Disease</td>
<td>U Virginia</td>
<td>AstraZeneca</td>
</tr>
<tr>
<td>Schizophrenia</td>
<td>Yale</td>
<td>Pfizer</td>
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<tr>
<td>Schizophrenia</td>
<td>Indiana U</td>
<td>Lilly</td>
</tr>
<tr>
<td>Smoking Cessation</td>
<td>VCU/Pittsburgh</td>
<td>Janssen</td>
</tr>
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- Translational Innovation Success Measures
  - Does use of template agreements speed negotiation time?
  - Does crowdsourcing of indications generate new ideas?
  - Do studies result in new indications/approvals?
NCATS Support Leads to Clinical Trial to Test Repurposed Cancer Treatment as Alzheimer’s Therapy

As Baby Boomers get older, the number of people with age-related conditions such as cancer and Alzheimer’s disease continues to grow. Alzheimer’s disease is the most common form of dementia, a group of disorders that cause progressive loss of memory and other mental processes. About 6 million Americans have Alzheimer’s disease, and current drug therapies can only ease symptoms of the disease without stopping its progression. New treatments — so-called disease-modifying therapies — are needed to halt Alzheimer’s by targeting its underlying mechanisms.

Blocking that path to therapeutic success is the costly, complex process of drug development. The average length of time from discovery of a therapeutic target to approval of a new drug is about 14 years. The failure rate during this process exceeds 95 percent.

NCATS is addressing these translational bottlenecks through programs such as the Discovering New Therapeutic Uses for Existing Molecules (New Therapeutic Uses) program. Launched in 2012, this initiative matches academic researchers with pharmaceutical industry assets that have undergone significant research and development to accelerate the process of finding new therapies.

Now, NCATS is celebrating one of the first promising results from the New Therapeutic Uses program: Center-supported scientists at Yale University School of Medicine have found that an experimental compound originally developed as a cancer therapy potentially could be used to treat Alzheimer’s disease. The compound successfully reversed brain problems in mouse models of the condition, and now the researchers are testing it in humans. The results of the animal study were published for early view on March 21, 2015, in the Annals of Neurology. Read the NIH news release.
NCATS Division of Preclinical Innovation
A Collaborative Engine

Project Entry Point

Target Validation > Assay Dev > Probe/Lead Development > Lead Optimization > Preclinical Development

Target

Unvalidated target
Validated target
Target assay
Lead compound
Preclinical development candidate

DPI Program

Assay, Chemistry Technologies > Tox21 (Systems Toxicology) > BrIDGs

RNAi > NCGC > Therapeutics for Rare/Neglected Dis (TRND)

Stem Cell Technology Facility

DPI

Deliverables

Genome-wide RNAi systems biology data
Chemical genomics data
Stem cell tools/data
Leads for therapeutic development
Predictive in vitro toxicology profiles
Approved drugs effective for new indications
Drugs suitable for adoption for further development
New drugs for untreatable diseases
Novel clinical trial designs

More efficient/faster/cheaper translation and therapeutic development

NIH

National Center for Advancing Translational Sciences

NCGC

FDA approval

I
II
III

FDA approval

Clinical Trials

I
II
III
Collaborator: Vasilis Vasiliou, Yale University

Target: ALDH1A1

Therapeutic Scope: Cancer, Inflammation, Obesity, Development

Objective: Identification and characterization of small molecule inhibitors of Aldehyde Dehydrogenase isoform 1A1

Discovery of NCT-501, a Potent and Selective Theophylline-Based Inhibitor of Aldehyde Dehydrogenase 1A1 (ALDH1A1)

Shyh-Ming Yang,† Adam Yasgar,† Bettina Miller,† Madhu Lal-Nag,‡ Kyle Brimacombe,† Xin Hu,‡ Hongmo Sun,† Amy Wang,† Xin Xu,† Kimloan Nguyen,† Udo Oppermann,§,‖ Marc Ferrer,† Vasilis Vasiliou,‡,† Anton Simeonov,† Ajit Jadhav,† and David J. Maloney*†
Drug Repurposing

Screen → Hit → Lead → Lead Optimization → Preclinical Development → Clinical Trials → FDA approval

>500,000 compounds, 15 yrs

1-2 years?

Target

3000 drugs

>500,000 compounds, 15 yrs

3000 drugs
NCATS Comprehensive Repurposing Program
“Systematizing Serendipity”

The NCGC Pharmaceutical Collection: A Comprehensive Resource of Clinically Approved Drugs Enabling Repurposing and Chemical Genomics

Ruili Huang,* Noel Southall,* Yuhong Wang, Adam Yasgar, Paul Shinn, Ajit Jadhav, Dac-Trung Nguyen, Christopher P. Austin†

Small-molecule compounds approved for use as drugs may be “repurposed” for new indications and studied to determine the mechanisms of their beneficial and adverse effects. A comprehensive collection of all small-molecule drugs approved for human use would be invaluable for systematic repurposing across human diseases, particularly for rare and neglected diseases, for which the cost and time required for development of a new chemical entity are often prohibitive. Previous efforts to build such a comprehensive collection have been limited by the complexities, redundancies, and semantic inconsistencies of drug naming within and among regulatory agencies worldwide; a lack of clear conceptualization of what constitutes a drug; and a lack of access to physical samples. We report here the creation of a definitive, complete, and nonredundant list of all approved molecular entities as a freely available electronic resource and a physical collection of small molecules amenable to high-throughput screening.
Identification of repurposed small molecule drugs for chordoma therapy

Menghang Xia,¹,† Ruili Huang,¹† Srilatha Sakamuru,¹ David Alcorta,² Ming-Huang Cho,¹ Dae-Hee Lee,³ Deric M Park,³ Michael J Kelley,² Josh Sommer,¹ and Christopher P Austin¹

³NIH Chemical Genomics Center; National Institute of Biomedical Imaging and Bioengineering; National Human Genome Research Institute; National Institute on Aging; ²Department of Medicine; Duke University; ¹National Center for Advancing Translational Sciences; National Institutes of Health

Keywords: chordoma, NCGC, pre-mRNA splicing

ARTICLE
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DOI: 10.1038/ncomms1044

Induction and reversal of myotonic dystrophy type 1 pre-mRNA splicing defects by small molecules

Jessica L. Childs-Disney¹,†, Ewa Stepieniak-Koniczewska²,†, Tuan Tran¹,³,†, Ilyas Yildirim²,‡, Hajeung Park¹, Catherine Z. Chen⁵, Jason Hoskins⁶, Noel Southall⁵, Juan J. Marugan⁶, Samarjit Patnaik⁵, Wei Zheng⁵, Chris P. Austin⁵, George C. Schatz⁴, Krzysztof Sobczak², Charles A. Thornton⁶ & Matthew D. Disney¹
Partnering with Disease Foundations to Speed Drug Discovery

When scientists who specialize in drug development have a promising idea for a new disease treatment, they often start by designing biological tests called assays. By using high-throughput (robotically assisted) screening, researchers use the assays to evaluate hundreds of thousands of compounds with the potential to become new treatments. This complex process requires teamwork to involve the right types of expertise and perspectives in the research project team.

Designing high-throughput screening assays is a science in itself. The team must have in-depth familiarity not only with assay technology but also with the target disease and its unique challenges. When the disease is rare, limited information can present additional challenges.

As director of NCATS' Assay Development and Screening Technology Laboratory, Jim Inglese, Ph.D., leads a team of experts who take on these challenges every day. To increase the likelihood of success, Inglese encourages postdoctoral researchers who are knowledgeable about specific diseases to join project teams through fellowships sponsored by patient groups and foundations.

These fellows bring strong disease expertise to NCATS, where Inglese mentors them in broad translational capabilities including assay development and early drug discovery. The overall goal is to develop new technologies and methods to build better disease models that can help advance the search for potential treatments.

http://ncats.nih.gov/pubs/features/adst-fellows

Hannah’s Hope Fund

Charcot-Marie-Tooth Association

Michael J. Fox Foundation

Alpha-1 Foundation

Lori Sames, founder of Hannah’s Hope Fund, and her daughter Hannah, who has giant axonal neuropathy, a progressive neurological condition. (Lori Sames Photo)
NCATS - Children Tumor Foundation (CTF) Collaboration

**PIs:** Annette Bakker (CTF), Jaishri Blakeley (JHU), Marc Ferrer (NCATS)

**Disease focus:** Neurofibromatosis 2 (NF2), characterized by multiple tumors on cranial and spinal nerves, and other lesions of the brain and spinal cord.

**Goal:** Discover new single drug and drug combination treatments for NF2.

**Scope/Progress:** CTF investigators (Synodos collaborative project funded by CTF) provided NCATS with NF2 Schwannomas and Meningiomas that have been screened with the NCATS MIPE 4.0 oncology collection (1,913 compounds). Selected compounds are being screened in dose response matrices to discover synergistic combinations.
The Learning Collaborative: Capitalizing on Strengths

- Bench to bedside translation in drug repurposing
- National leadership in medicinal and pharmaceutical chemistry
- Pharma experience
- ~ 400 active research projects
- World-wide network of blood cancer experts
- Track record of commercial partnerships
- Pharma experience
- Focus on rare and neglected diseases
- Industrial scale HTS, cheminformatics, medicinal chemistry, drug development capabilities
- Pharma experience
NCATS Therapeutics Development Programs

Therapeutics for Rare and Neglected Diseases (TRND)
Bridging Interventional Development Gaps (BrIDGs)

**Model:** Collaboration between NCATS labs with preclinical drug development expertise and external organizations with disease area/target expertise

**Projects:**
- Entry from Probe to IND-enabling
- Exit by adoption by external organization for completion of clinical development
- Serve to develop new generally applicable platform technologies and paradigms

**Eligible Collaborators:**
- Academic, Non-Profit, Government Lab, Biotech, Pharma
- Ex-U.S. applicants accepted
TRND Niemann-Pick C Disease Collaborative
NIH teams with industry to develop treatments for Niemann-Pick Type C disease.

Researchers from the National Institutes of Health have entered into an agreement with biotechnology company Vtesse, Inc., of Gaithersburg, Maryland, to develop treatments for Niemann-Pick disease type C (NPC) and other lysosomal storage disorders.

Lysosomal storage diseases, also known as lipid storage diseases, comprise about 50 rare inherited disorders that usually affect children. Fatty materials accumulate in the cells and tissues of the body. These diseases can result in damage to the brain, peripheral nervous system, liver, and other organs and tissues; they are often fatal.

Researchers at the National Center for Advancing Translational Sciences (NCATS) and the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), both parts of NIH, will conduct studies on NPC and other lysosomal storage disorders with funding provided by Vtesse.

“This is an excellent example of how launching a project to study the underlying biology of one disease can lead to advances that hold promise for an entire group of diseases — the NCATS goal of finding what is common among diseases and the translational science process,” said NCATS Director Christopher P. Austin, M.D. “I am grateful to all of the NPC patients, their families and patient support groups who have been equal partners in our efforts to find therapeutic solutions to these devastating disorders.”

“Our role is to test promising new drugs and therapies to ensure that they are safe and effective.”

—Periye D. Porter, M.D., Ph.D.
NCBD Clinical Director
GOAL: Develop an *in vitro* platform that uses human tissues to evaluate the efficacy, safety and toxicity of promising therapies.

**Current Goals:**
- Integration
- Compound testing
- Validation
- Partnerships
- Adoption by community
Tissue Chip Consortium

NIH - FDA - DARPA

- Share expertise, materials
- Hold joint semi-annual meetings
- Provide a common set of validation compounds
- Facilitate collaborations

Biotech/Industry Partnerships

Heart-Vasc-tumor
WashU

Heart-Lung
Wyss

Liver
Pittsburgh/MSGH

Muscle/TEBV
Duke

Brain
U Wisconsin

Human Organs on a Chip
Wyss

Heart-liver-WAT
UC-Berkeley

Kidney
U Washington

Skin
Columbia

Gut-Disease
Johns Hopkins

Female Repro
Northwestern

Gut innervation
Cincinnati Children’s
Johns Hopkins

Liver-Metastasis
MIT

Neurovascular
Vanderbilt/Cleveland Clinic

BIO-MIMETICS
MIT/Draper Labs

Heart-Liver-Vascular
Columbia
Uniqueness of NCATS Portfolio

- Significant number of inventions relate to new therapeutic molecules and novel processes
- Inventions are much more advanced compared to other ICs
  - Indicators of high impact on facilitating translation of biomedical discoveries:
- High percentage of jointly owned inventions
  - Reflect the culture of NCATS aimed at using collaborations, alliances and partnerships to enhance positive outcomes and new cures
Snapshot of Inventive Activity at NCATS—Highly Collaborative Investigators

- Total Inventions: 130
- NCATS Solely Owned: 30
- Joint Inventions: 100
  - With other NIH Institutes: 37
    (NCI-CCR, NIDDK, NHGRI, NIAID, NHLBI, NIAMS, etc.)
  - With outside entities (majority academics): 63
NCATS Licensing Webpage

http://www.ncats.nih.gov/licensing.html

- Illustrates both Stage of Development and Indication
- Provides non-confidential information
- New format increased traffic by 250%
- Encourages discussion
I-Corps™ Training Program at NCATS

• Developed at NSF: Innovation Corps (I-Corps™)

• Intensive *Entrepreneurial Immersion* course aimed at providing teams with skills and strategies to reduce commercialization risk

• Curriculum emphasizes *Reaching out to Customers* to test hypotheses about the need and market for the technology being developed.
  - Each team is expected to conduct over 100 interviews over 10 weeks.

• Format is focused on *Experiential Learning*
Arithmetic to Log-Phase Growth: NCATS CTSA I-Corps *Train-the Trainer* Program

- NCATS is training new I-Corps educators at CTSA institutions who in turn can provide entrepreneurship training for other translational scientists
- NCATS provided supplements to active CTSA grants to participate in the I-Corps Train-the Trainer Program
- 10 CTSAs were awarded supplements and are participating in the pilot program
- Plan is to expand program to other CTSAs utilizing feedback and learnings from pilot program
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